

## A Researcher's Guide to Patents<sup>1</sup>

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The word "patent" is commonly used in our daily discussion. Advertisements proudly imply that their product is great because it is "patented." News anchors lead off a story stating that Company X is "protecting its patent" by suing Company Y. Researchers often read a patent and decry that the patent prevents them from working in the field. Although nearly everyone uses the word "patent" in their daily discussion, few individuals really understand what a patent is and why it exists. One of the objects of this paper is to provide a better understanding of patents: "the good, the bad and the ugly."

The word "patent" is also thrown around by those in the chemical and biotechnology fields. In biotechnology, it is relatively common for those in the field to share material, e.g. cells, plasmids, DNA, and the like. But what are the consequences, if any, of such sharing? This paper will attempt to answer that question also.

### WHAT A PATENT IS AND IS NOT

Is a patent a positive right? Let's suppose that Sid invents the pencil and receives a patent that covers pencils. Nancy thereafter invents a pencil having an eraser attached to one end and obtains a patent on her pencil with an eraser. In view of the fact that Nancy has a patent, does Nancy have a right to sell her pencils with an attached eraser? After all, Nancy has a patent, so doesn't that give her the right to sell her patented product?

Because we asked the question, you probably can guess that the answer is no. Having a patent to the pencil with an attached eraser does not give Nancy an automatic right to sell her pencils with an eraser. First, there may be regulatory reasons why she can't sell her product. Second, note that her pencil with an attached eraser is still a pencil. Any manufacture, use, sale, importation, or offer for sale would be an infringement of Sid's patent to the pencil. In accordance, Nancy cannot sell her pencils without Sid's

permission, and Sid can refuse such permission during the life of his patent.

Thus, patents are negative rights, not positive privileges. A patent provides its owner with the right to prevent the manufacture, sale, use, importation, or offer for sale of the patented product, process, or composition. A patent is not a positive right that enables its owner to do anything that he or she wants. This really isn't any different from many other property rights. For example, owning a car doesn't give you the right to drive it. You need a driver's license, license plates, insurance, etc. Owning a car, as indicated by a title, does, however, provide you the right to prevent others from driving your car. So, how can we tell what is covered by the patent?

### WHAT DOES A PATENT PROTECT?

Patents are comprised of a specification and claims. The specification is a written description of the invention. It must describe the invention so that those skilled in the art related to the invention, e.g. one typically involved in that area of endeavor, can make and use the invention. The claims describe what is to be protected by the patent. Grammatically speaking, a claim is the object in the sentence that begins "I claim. . ." Because such claim is a list of elements describing the invention where each of the elements may have descriptive clauses or subelements, thus the claims are the metes and bounds of the patent, and they must carefully cover the intellectual property whose protection is sought. For example, although the patent specification may disclose compounds A, B, C, D, and E, if only compounds A and B are claimed, then compounds C, D, and E are not covered by the patent. Occasionally, e.g. in the case of a pioneering invention, a court may extend the scope of a claim to equivalents. However, in general, claims are strictly construed by the precise language. In many cases, claims can be avoided by designing around the elements of a claim. Often, changing but a single element in a claim will be sufficient to avoid infringement. Patent professionals can assist in interpreting claims and provide advice to scientists who wish to avoid infringement of patent claims.

### WHY DO WE HAVE PATENTS?

Is it to reward inventors? Is it to make startup companies rich? Not really. Article 1, Section 8 of the

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U.S. Constitution states that “To promote science and the useful arts, Congress” can grant patents for a limited time to inventors and authors. Thus, the purpose is not to make inventors rich; in fact, very few patents are commercially successful. The purpose of patents is to encourage inventors to make an investment in time and money in research and development by providing exclusive rights for a limited time in exchange for an early public disclosure of the invention. Once a patent is granted, it is common that others will then improve the patented invention in their attempt to design an invention that doesn’t infringe the patent.

A key part of the patent process is publication to advance the state of the art. Such publication occurs early in the patenting process typically before claims are examined. As a result, published patent applications generally have overly broad claims covering subject matter that may not be patentable. Although you don’t have to stop your practices that are covered by a published patent application, you should be aware that you might be subject to retroactive infringement if a patent may someday be issued with similar claims that cover an invention that you are practicing.

## THE PATENT PROCESS

After an invention is conceived, a patent application can be filed. If the invention was made in the United States, the patent application will be filed in the United States first. Patents are granted on a country-by-country basis. In other words, a U.S. patent only provides protection in the United States. If you want patent protection in Brazil, you need to file a patent application in Brazil. Many European countries have banded together to form the European Patent Office, which allows examination of a single application. When a patent is granted by the European Patent Office, it is effective for any of the member countries by paying the appropriate fees and having the patent translated into the language of the country. In some countries, patents are not examined, which provides opportunities for multiple patents with conflicting claims or claims clearly covering prior art. Such unexamined patents are of concern only in the country that issued the patent. In most countries with well-developed economies, patents are examined to allow only claims that are useful, novel, and patentable (i.e. inventive or not obvious). As a result, patents issuing in Europe, Japan, and the United States often have scope that is significantly reduced from those in the published applications.

As noted above, generally an inventor will start the process by filing a patent application in his home country. If protection is desired in foreign countries, corresponding patent applications should be filed within 1 year of the original filing date. By filing

within 1 year, the foreign patent application is awarded the same filing date as the original patent application. In accordance, only prior art that has a date before the original filing date can be cited by the foreign patent office to establish that the claimed invention is not new and, therefore, is not patentable. Intervening publications between the original filing date and the date of foreign filing will not serve as prior art in the examination of the foreign patent applications. If the foreign patent application is not filed within the year, then any publication before the foreign filing date can be used as prior art to prevent the granting of patent claims. The 1-year grace period in which to file patent applications in other countries is limited to those countries that are members of an international treaty known as the Paris Convention of 1883. The Paris Convention is a treaty that has been signed by most, but not all, of the countries of the world. To preserve patent rights in those countries that are not members of the Paris Convention or do not have a bilateral agreement with country of origin, an inventor must file a patent applications in such countries as soon as possible, at least before any publication, disclosure, or public use of invention.

The United States, however, does not allow resident inventors to file a patent application in a foreign country without first having a license to do so. Most of the time, a license is granted at the time that the U.S. Patent Office sends the applicant a filing receipt. If a license is not indicated on the filing receipt, the applicant must wait for 6 months after filing before any application can be filed in a foreign country. A license is automatically granted 6 months after filing unless the U.S. Patent Office issues a secrecy order. An order to keep the patent application secret is issued by the U.S. government if the government considers the invention to be one of national security.

## FILING OUTSIDE THE UNITED STATES

Foreign filing of patents is very expensive. The major expense is due to the need to translate the patent application into multiple languages. It is not uncommon for foreign filing of patent applications to cost hundreds of thousands of dollars. Unfortunately, to obtain the benefit of the Paris Convention, patent applications had to be filed in foreign countries in the language of that country within 1 year of the original filing. It was not uncommon for tens or hundreds of thousands of dollars to be spent on foreign translations required for foreign filing only to abandon the project a year or two later when it was found that the invention lacked promise. To minimize that problem, the Patent Cooperation Treaty (PCT) was initiated. Under the PCT, a patent applicant can file its “foreign” applications in all member countries (currently 179) by filing a single PCT application in the English, French, or German language.

If the PCT application is filed within 1 year of the original filing, the priority date benefit of the Paris Convention is obtained for those countries that are members of the PCT. Translations of the PCT application are not needed until 30 months after the original filing date. In that way, the applicant has more time to decide whether the major expense of translation is necessary. Applicants often designate all 179 member countries at the time of filing, and later, as costs accrue for applications in each country, applicants opt out of many countries, retaining applications only in countries with a significant commercial market for the invention.

It should be noted that in most foreign countries the first person to apply to the Patent Office on a particular invention gets the patent, whereas in the United States the first person to invent a particular invention gets the patent. Hence, even if one files an application in the U.S. Patent Office before another person, if the first applicant was not the first inventor, the patent may be awarded to the later filing applicant. The decision as to which person was the first to invent is made by the U.S. Patent Office after an "interference proceeding."

#### **WHAT IS PATENTABLE AND HOW DO MATERIAL TRANSFER AGREEMENTS (MTAs) AFFECT THE PROCESS?**

Patents are granted for almost anything found in our homes and workplaces that has been made by man. Patents are granted for machines such as thermocyclers, mass spectrometers, and coffee makers. Patent are granted on manufactured goods such as 96-well plates or molded flower pots. Patents are granted on compounds such as polymerase or an isolated and purified gene (the gene in its native state is not patentable) or a plasmid. Patents are granted on compositions such as a novel mixtures of known compounds for a particular use. Patents are granted on processes such as a process to amplify DNA, a process of achieving a trait by changing the expression of a gene, a process of applying an algorithm, or a process to sequence DNA. Patents are granted on new life forms such as oncogenic mice and transgenic tomatoes.

When a researcher transfers a material, e.g. plasmid or cell, to another person, it is possible that the recipient may improve the material and make a patentable invention. MTAs often have patent clauses. A recipient may prefer a patent clause stating that the recipient will own all patents on new inventions or discoveries made from the recipient's use of the material. Alternatively, a donor may request a patent clause requiring that a license is granted back to the donor to practice under any patent resulting from the recipient's work using the transferred material. Such a grant back license is a promise from the future inventor that he will not exercise his negative rights

to exclude the donor from practicing the results of the work using the material. Such licenses are often limited in scope to research or a particular field.

A recipient inventor cannot typically get a patent on the material, *per se*, because the recipient was not the inventor, unless perhaps the donated material was uncharacterized. For instance, if the donated material is a genomic clone library, a recipient who isolates and discovers a previously undefined gene within the library may be able to patent the new isolated gene, but the donor is still free to use the library.

In general, a recipient can potentially get patents for new inventions or discoveries made using donated material. For instance, suppose Sid uses an MTA to express his expectations surrounding the delivery to Nancy of a plasmid with Sid's favorite gene linked to a promoter. The agreement says Nancy is free to use the plasmid for any research and that Nancy can have sole right to any inventions that she makes using Sid's plasmid. Sid does bargain for and gets Nancy to promise to pay a 10% royalty on sales of transgenic plants made with Sid's plasmid. Nancy uses the plasmid to make transgenic plants that produce bananas that are odious to monkeys and still tasty to humans, and Nancy seeks patent protection on claims that might be commercially useful in banana plantations located in Simia—a country where hunters are used to keep monkeys from decimating banana plantations. The Simia Patent Office issues to Nancy a patent with claims that read:

I claim:

1. A method of using the "Sid" plasmid in a DNA construct in transgenic bananas whereby the bananas are rendered odious to monkeys.
2. Transgenic banana fruit comprising the "Sid" plasmid.

Nancy does not file her patent application in other countries because the monkey problem is nonexistent or at least minimal in other banana republics. Nancy's negative rights under the Simian Patent are effective only in Simia and only cover the method of using the "Sid" plasmid in bananas and the resulting transgenic banana fruit. Sid and other researchers in Simia are free to use the Sid's plasmid in other organisms, e.g. any animal and all other plants except banana. And, because Nancy has no patents in other countries, she has no right to restrict the production of transgenic bananas in those other countries. Nancy's ability for exclusive use in bananas will provide her an incentive to develop commercial plants free of competition for the limited life of the patent in Simia. Because there are thousands of banana farmers and one boat dock in Simia, Nancy minimizes her accounting work by donating transgenic banana plants and collecting a royalty on exported transgenic bananas at the dock. Alas, poor Sid gets no royalty on sales of transgenic plants because a 10% royalty of no sales is nothing. However, Sid still has the pencil

monopoly. And, although the monkeys of Simia may not have tasty bananas, they will learn to be happier to eat other plants in peace with less fear of the banana militia.

#### SUMMARY

Patents confer negative rights, i.e. the right to exclude the making, selling, or using of the claimed

subject matter. Subject matter disclosed in a patent but not expressly and precisely claimed is in the public domain. Patents apply only in the country that issues the patent. MTAs often have patent clauses expressing the expectations of the donor and recipient on exclusivity or licenses under patents for new, useful, and patentable inventions made using the donated material.